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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,763	10/31/2003	Michael J. Botich	P01404US3	2804
650/08 7590 12/15/2008 STOEL RIVES LLP 201 SO. MAIN STREET, SUITE 1100 ONE UTAH CENTER SALT LAKE CITY, UT 84111				
EXAMINER STIGELL, THEODORE J				
ART UNIT 3763		PAPER NUMBER		
MAIL DATE 12/15/2008		DELIVERY MODE PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/698,763

**Applicant(s)**

BOTICH ET AL.

**Examiner**

THEODORE J. STIGELL

**Art Unit**

3763

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 9-20, 22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9-20, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/9/2008 has been entered.

#### ***Drawings***

The objections to the drawings have been withdrawn in light of the amendments to the specification filed on 10/9/2008.

#### ***Specification***

The objections to the specification have been withdrawn in light of the amendments to the specification filed on 10/9/2008.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5 and 9-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Shaw (5,779,679). Shaw discloses a medical device (10) comprising a housing (12) having an aperture (44) in a wall of the housing, the aperture defined by a rim (42), a first needle (16) operable between an extended position (Figure 1) in which the needle is exposed and a retracted position (Figure 2) in which the needle is shielded, a biasing element (15) biasing the needle to the retracted position, a needle hub (14) defining a forward end (distal half of the middle portion of 14) and a rearward end (proximal half of the middle portion of 14), wherein the needle hub displaceable between a forward position in which the first needle is in the extended position and the forward end of the needle hub is within the housing (at least a portion of the forward end is in the housing, see Figure 1) and a rearward position in which the first needle is in the retracted position (see Figure 2), the needle hub comprising a first connector (32) at an end of the hub, the first connector configured to provide a fluid-tight connection between a fluid line and the first needle, an actuator (38) configured to cooperate with the rim of the housing to releasably retain the needle in the extended position against a bias from the biasing element, wherein the actuator is configured to be moved out of engagement with the rim to permit the bias to transition the needle hub to the rearward position, wherein the actuator comprises a forward stop (front end of 40) configured to cooperate with housing to impede forward axial movement, wherein the actuator is configured to be outside the housing when the needle hub is in the rearward position (at least a portion of the actuator is outside the housing in the rearward position), a flange (under end of 40) projecting from the needle hub, a lip (46, 47, lips disclosed in column 6, lines 37-40)

projecting inwardly from the wall to engage the flange to prevent further axial displacement, further comprising a pair of wings (18, 20) connected to the housing, wherein the wings are displaceable about a longitudinal axis of the housing and wherein a portion of the wings are disposed forwardly of the aperture in the housing, and wherein a majority portion of the needle hub is displaced outside the housing in the rearward position. It is the examiner's position that Shaw discloses the method recited by the applicant.

### ***Double Patenting***

The terminal disclaimer provided on 10/9/2008 has been accepted and therefore the double patenting rejection has been withdrawn.

### ***Response to Arguments***

Applicant's arguments filed 10/9/2008 have been fully considered but they are not persuasive.

In response to the applicant's argument that Shaw fails to disclose a forward end of the needle hub being within the housing in the forward position, the examiner respectfully disagrees. The forward end of the needle hub of Shaw as currently defined is at least partially confined within the housing in the forward position.

In response to the applicant's argument that Shaw fails to disclose an actuator that is configured to be outside the housing when the needle hub is in the rearward position, the examiner respectfully disagrees. The actuator of Shaw as currently defined is at least partially outside the housing in the rearward position.

***Conclusion***

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THEODORE J. STIGELL whose telephone number is (571)272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Theodore J Stigell/  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763